



DEC - 2 2003

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In re Application of  
Michael Graupe et al  
Serial No: 10/035,783  
Filed: December 24, 2001  
Attorney Docket No. 1016US

## PETITION DECISION

This is in response to applicants' petition under 37 CFR 1.144 filed September 10, 2003.

### BACKGROUND

A review of the file history shows that this application was accepted under 35 U.S.C. 111 on December 24, 2001. The application as filed contained claims 1-31. In a first Office action mailed November 6, 2002, the examiner set forth a restriction requirement under 35 U.S.C. 121 dividing the claims into four groups and requiring an election of species within the elected group, as follows:

Group I, claims 1-9, 13-15, and 28-31 (in part) drawn to compounds, compositions, methods of use and a process for the preparation of compounds of Formula I wherein  $X_1$ ,  $R^3$ , and  $R^4$  substituents are non heterocyclic compounds classified in class 558, various subclasses.

Group II, claims 1-7, 10-12, 16-18, 19-21, 22-24 and 28-31 (in part) drawn to compounds, compositions, methods of use and process for preparing the compounds of Formula I wherein  $X_1$ ,  $R^3$ , and  $R^4$  substituents are oxazol, morpholine, pyrrole, piperidine etc., classified in classes 544-548, various subclasses.

Group III, claims 1-7 and 25-31 (in part) drawn to compounds, compositions, methods of use and process for preparing the compounds of Formula I wherein  $X_1$ ,  $R^3$ , and  $R^4$  substituents are azetidine, azepane morpholine etc., classified in classes 540-548, various subclasses.

Group IV, claims 1-7 (in part) drawn to compounds, compositions, methods of use and process for preparing the compounds of Formula I which are not found in any of the above classes.

Each of the Groups required a single disclosed species to be presented upon election.

Applicants responded on May 5, 2003, electing Group II. Applicants elected a species as required. Applicants traversed the requirement and argued that the examiner had imposed a restriction requirement which divides the claimed invention into four subgenera and alleged that the prevailing law prohibits the use of 35 U.S.C. 121 in this manner.

A first action on the merits was mailed to applicants on June 11, 2003. The examiner stated in response to the traversal that the restriction of a Markush group is proper wherein the compounds do not share a structural feature that is disclosed as being essential to the disclosed utility and made the restriction final.

Applicants responded to the office action on September 15, 2003, and filled this petition concurrently.

## DISCUSSION

Upon review of the restriction requirement, it has been noted that the only structural feature that is common to all the alternatives is an amide, and that this is not constitute a substantial structural feature essential to the disclosed utility. While amides are known to have various utilities the common amide structure herein is not the element which provides the disclosed utility. However after stating this it is noted that the restriction, itself, has major problems.

Groups II, III and IV are not defined to the extent that all the members of the group are delineated clearly such that applicants can make an informed choice of a single group above. For example there is a set of heterorings found in Group II but it is not an exhaustive list of what heterorings applicant would be entitled to if that group were selected. Group II and Group III an overlap with the same morpholine moiety being present in both groups. Groups II and III have the  $X_1$ ,  $R^3$ , and  $R^4$  moieties all including a ring. The restriction does not include a choice wherein there is one or more rings for  $X_1$ ,  $R^3$ , and  $R^4$ . Group IV is drawn to compounds that are not found in the other groups. Since the other groups are not fully defined it is unclear what compounds are found in this group.

Applicants argue that the examiner has, in effect, made an improper Markush group rejection with the restriction requirement. This is incorrect. The examiner has attempted, albeit poorly, to determine what inventions applicants are claiming. A review of claim 1, alone, which contains only three variables,  $X_1$ ,  $R^3$ , and  $R^4$ , attached to a small common core encompasses literally millions of compounds which have in many instances little or no relationship to each other except the small common core. However, this core is not the structure which provides the disclosed utility. Thus claim 1 encompasses a plethora of different Markush groups based on the principles enunciated in *In re Haas* and *In re Weber*, both cited by applicants in their argument, and allows an examiner to restrict the groups based on significant structural elements coupled with disclosed

utility. Following such restriction requirement a proper election of species within an elected group may be required. Such action does no disservice to applicants as all proper Markush groups are, or may be, examined in proper order. Although applicants here argue that the facts herein are similar to those ruled on in *In re Haas* and *In re Weber*, it is noted that in both cases cited a restriction requirement was made between a small or limited number of individual species in a Markush group, each having the same significant structural element which was essential to the disclosed utility. Here there are millions of compounds, not a small or limited number, and there is no significant structural element essential to the disclosed utility. In fact, it is entirely likely that some, if not many, of the compounds encompassed by the claims are known, but it is impossible for the examiner to discover these without limiting the number of compounds to be considered via a proper restriction requirement. The simplest compound encompassed by the claims appears to be  $(H_2NCH_2)_2CH-C(O)-NH-CF_2CHO$  which includes the  $CH-C(O)-NH-$  core. Many more complicated structures, including many with heterocyclic rings are encompassed by the generic structure of claim 1 and have no relationship with or apparent common activity with this simplest compound. Applicants' claims are especially confusing as all of the three main variables are defined by a second set of variables which include further variables which include additional variables.

Applicants further refer to the guidance found in M.P.E.P. 803.02. This guidance is appropriate for an election of species within a Markush group, but not for the main requirement for restriction.


The restriction requirement, as written, is therefor incomplete and unclear and is not based on significant structural features which support the disclosed utility of the claimed inventions as required by case law and M.P.E.P. 800.

#### DECISION

Applicants' petition is **GRANTED** for the reasons set forth above. The Office actions are vacated in view of the deficiencies of the restriction requirement as originally set forth.

The application will be returned to the examiner for further action not inconsistent with this decision, which may include a proper restriction requirement and consideration of applicants' reply of September 15, 2003.

Should there be any question to this decision, please contact William Dixon, by mail addressed to: Director, Technology Center 1600, PO Box 1450, Alexandria, VA 22313-1450, or by telephone (703) 308-3824 or by facsimile transmission at (703) 305-7230.

  
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